Purpose. We investigated the incidence and extent of stent migration after endovascular sealing of abdominal aortic aneurysms (EVAS), its relationship with adherence to the instructions for use of the Nellix endograft and its association with aneurysm growth.

Methods. In this retrospective single centre study, the clinical data and follow-up CT images of patients undergoing infra-renal EVAS with a minimum follow-up of 1 year were reviewed. The first postoperative CT scan at one month and the subsequent scans were used to measure the distances between the proximal end of the stent and reference visceral vessels using a previously validated technique. Device migration was based on the Society of Vascular Surgery definition of >10mm downward movement of either Nellix stent in the proximal landing zone; furthermore, we defined proximal displacement a downward movement of ≥4mm. Patients were categorised according to adherence to the old (2013) or new (2016) Nellix IFU. Aneurysm diameter was measured for each scan and a change of ≥5mm was deemed indicative of aneurysm growth.

Results. Seventy-five patients were eligible for inclusion in our study. Over a 4-year period, migration ≥4mm occurred in 42 (56%) patients and migration of ≥10mm in 16 (21%), with similar incidence in right and left stents. Migration ≥4mm was significantly more frequent among patients whose anatomy did not conform to any IFU (p=0.025). Presence of aneurysm growth ≥5mm was observed in 14 patients (19%) and was significantly associated with proximal displacement ≥4mm (p=0.03).

Conclusion. Infra-renal EVAS may be complicated by proximal displacement and migration, particularly when performed outside IFU. The definition of migration used for EVAR is inappropriate for EVAS; a new consensus on definition and measurement technique is necessary.

Introduction

Endovascular aneurysm sealing (EVAS) performed with the Nellix® endoprosthesis (Endologix Inc., Irvine, California, USA) received Conformité Européenne marking in April 2013 and was only recently introduced in clinical practice.[1,2,3] Long term follow-up data is limited, however, type Ia, type Ib, and type II endoleaks have been reported in multiple studies.[4,5,6,7,8] Migration has also been described in recent literature.[6,7,8,9,10] Early outcomes dictated a change in the instructions for use (IFU) in October 2016, with modifications aimed at reducing the occurrence of migration. The aim of this study was to establish the incidence of stent movement and migration after infra-renal EVAS, its relationship with adherence to IFU and its consequences.

Methods

This project falls within a programme of studies evaluating EVAS at our institution, therefore, formal ethical approval was not required; the study was registered as a service review.

Study design and Inclusion criteria

This was a retrospective, single centre, observational study on patients treated with infra-renal EVAS. For inclusion, all patients were required to have had a baseline postoperative CT scan at 1 month (≤6 weeks after device implantation) and at least 1 additional CT scan (minimum of 12 months from the initial implantation procedure) available in the Digital Imaging and Communication in Medicine (National Electrical Manufacturers Association, Rosslyn, Va, USA) format. Our study excluded: patients in whom CT images were not available, patients undergoing EVAS extending into the supra-renal segment (with chimneys), patients undergoing EVAS as a secondary intervention (after previous aortic aneurysm surgery) and patients treated for ruptured aneurysms.

Outcome measures and Definitions

The outcome measure of the study was the incidence of migration as well as its relationship with adherence to IFU and aneurysm growth. The reporting standards of the Society for Vascular Surgery (SVS) define device migration as movement of >10 mm relative to anatomical landmarks or any migration leading to symptoms or requiring therapy.[11] England et al specifically defined stent migration for the EVAS device in a recent study as ≥4mm relative to a vascular landmark.[12] This cut-off has also been used to define migration in fenestrated endovascular grafts.[13] Our method included assessing and reporting stent graft movement (≥4 mm), which we defined as proximal displacement in this manuscript, and migration (>10mm), as defined by the SVS. The instructions for use (IFU) of the Nellix device changed in October 2016, when more restrictive anatomical criteria were introduced.[14] We assessed if the aortic anatomy of the patients was within or outside the old IFU (IFU-2013)[15] or the new, refined IFU (IFU-2016).[14] Aneurysm diameter was measured as the maximum cross-sectional diameter on reconstructed slices perpendicular to the main aortic axis, measuring from adventitia to adventitia. Aneurysm growth was defined as a change of ≥5mm between the 1-month CT and subsequent scans.

Patient management and follow-up imaging protocol

EVAS was introduced in our institute in December 2013 under the supervision of our Techniques and Medical Devices group, with strict audit and reporting requirements. Informed consent was obtained for the procedure; this included an understanding that procedural outcomes would be evaluated and reported accordingly. Our follow-up protocol includes postoperative imaging by abdominal radiography on the first day; duplex ultrasound imaging and arterial-phase CT at 1 month; followed by yearly abdominal radiographs, duplex scans, and arterial-phase CT, except in patients with significant renal impairment who have uncomplicated 1-month CT appearances and favourable

anatomical features, as judged by an experienced operator (RM). CT data were reconstructed using the thinnest available slice (≤2 mm) before review.

Measurements[10]

The use of a Picture Archiving and Communications System (PACS) built-in 'vessel analysis' module (Carestream software version 11.4.1.1011; Carestream Health Inc., Rochester, NY, USA) enabled the measurement of stent movement. Each scan was loaded onto a PACS workstation to generate a semi-automated central luminal line (CLL) through each stent using the 'Aorta Protocol' tool in the vessel analysis software. The 'Aorta Protocol' made switching from left stent to the right, and vice versa, automated and provided a more unified generation of the stent CLL. The CLL of each stent was checked by scrolling through all the anatomical planes available: axial, coronal and sagittal; ensuring that it was indeed traveling through the centre of the luminal space. A two-dimensional oblique axial view, perpendicular to the CLL, was used to determine the position of the stent graft against the specified reference vessel. We defined this as the point most inferior of the superior mesenteric artery (SMA), where a clear separation of this vessel from the aortic wall was visible, seen on the first oblique axial CLL reformatted image. The distance between this point and the first oblique axial CLL reformat that contained at least two stent struts was measured, reducing the probability of mistaking calcification for the actual stent graft. Each CLL measurement was compared with the same measurement on the 1-year CT scan and, if available, subsequent scans. Measurement differences between the CT scan at 1 month and subsequent scans, for the same anatomic location, were used to determine whether device movement had occurred. Caudal movement was indicated by a positive value and cranial with a negative value. The bias (difference between true movement and the CT assessment), intra-observer and inter-observer variability when using this method for the movement definition of ≥4mm had been previously assessed.[12]

Data Analysis

SPSS version 22.0 (SPSS, Inc., Chicago, IL, USA) was used to analyse our data. Continuous variables were assessed for normality with the Kolmogorov–Smirnov test and presented as mean and standard deviation (SD) or median and range, according to the underlying distributions. Paired comparisons were performed with a t-test or Mann-Whitney U test. Kaplan-Meier survival curves were generated to visualise freedom from proximal displacement or migration patterns. The log rank test was used to compare proximal displacement or migration rates between different IFU groups. The Fisher's Exact test was used to assess the association of aneurysm growth with proximal displacement or migration.

Results

112 consecutive patients (86 men) with a mean age of 77 (SD: 7) years underwent EVAS between December 2013 and January 2018. The following patients were excluded: seven who underwent EVAS to reline previously inserted grafts; eleven chimney-EVAS patients; six who had missing post-operative scans due to loss to follow-up (2), death after 30 days but before 1 year (3) and severe renal impairment contra-indicating contrast CT (1); twelve who had not yet had their 1-year post-operative scan and one patient who underwent EVAS for a ruptured aneurysm.

Seventy-five patients (57 men) were included in this study with a mean age of 76 (SD: 7.6) years. All patients had a 1-year follow-up CT; forty-three had a 2-year post-EVAS CT; fifteen had a CT scan at 3-years; and two had a CT at 4 years. Pre-operative anatomical data is displayed in Table 1. The anatomical features of 20 patients (26%) were within both IFU-2013 and IFU-2016; 55 (72%) patients were within IFU-2013; of these, 35 were outside the new IFU-2016; 20 patients were outside both IFU-2013 and IFU-2016. EVAS was performed using paired stents in all but three patients, who received an aortouni-iliac (AUI) device.

There were no post-operative deaths but 19 patients (25%) experienced a complication within 30-days, of whom seven required a secondary intervention (Table 2). There was one operative type Ia endoleak, which resolved at 48 hours. Over the 4-year period, forty-two patients had proximal displacement of ≥4mm in one or more stents. 25 were first detected within one year (33% of the point population of 75), 12 were detected at two-year follow-up (28% of the point population of 43) and a further five at 3-year follow-up (33% of the point population of 15). Sixteen patients had migration of >10mm: 5 were first detected at one year (7%); 6 at two years (14%); 4 at three years (27%) and one at 4 years (50%). There were no differences observed in the incidence of proximal displacement /migration between the left and right stents irrespective of the definition (Table 3). Figure 1 shows the evolution of proximal displacement and migration in time.

Proximal displacement/migration was affected by compliance with IFU-2013 and IFU-2016, as summarized in Table 4. The highest incidence of proximal displacement (70% for a ≥4mm definition) was observed when the device was outside both IFUs; this reduced to 30% when the procedure was within the new IFU (IFU-2016).

Outcomes beyond 30 days included 8 deaths, none aneurysm related. Three patients, all with evidence of proximal displacement or migration, demonstrated a type Ia endoleak during follow up. A total of ten patients underwent late re-intervention of whom six had at least 4mm of proximal displacement and five had migration of at least 10 mm. The details of the re-interventions and their relationship with proximal displacement or migration are summarised in Table 5.

Figure 2 shows freedom from proximal displacement and migration for the left stent, right stent and the whole cohort. Figure 3 shows freedom from proximal displacement and migration of each of the IFU groups. Proximal displacement was significantly more frequent among patients whose anatomy did not conform to any IFU (p=0.025). During follow-up, 14 patients displayed aneurysm growth ≥5mm (median 5.5; range 5-15 mm). This was significantly associated with proximal displacement (p=0.03). In six patients proximal displacement preceded aneurysm growth, in three patients aneurysm growth preceded proximal displacement, in three patients proximal displacement and aneurysm growth were detected on the same scan; in two other patients, aneurysm growth was detected but there was no proximal displacement.

Discussion

This study confirms that proximal stent displacement occurs in a significant proportion of patients who undergo EVAS and is associated with anatomy outside the current IFU. Movement can be progressive, can affect one or both stents and is associated with aneurysm growth, a finding that had not been described before.

We had previously reported, in a much smaller cohort of patients with shorter follow-up, the occurrence of post-EVAS stent proximal displacement, defined as and measured with the same criteria used in the present study.[10] Migration and other types of stent displacement have also been described by other authors,[6,7,8,16,17,18,19] although definition and measurement techniques have not been consistent in the literature. In contrast, Van den Ham et al. did not observe migration in patient cohorts with high adherence to IFU at one year[20].

We chose to use two definitions for stent displacement, one being the SVS definition for EVAR (>10 mm), which is more than 15 years old[11]. We believe that this definition, whilst established in the literature, is outdated, partly because modern cross-sectional imaging allows the detection of much smaller stent movements, but also because of the inherent differences between EVAR and EVAS, which seals the aneurysm without active fixation at the landing zones (i.e. without radial force and/or hooks and barbs). As aortic necks are rarely perfectly cylindrical, even small post-EVAS stent movements may result in loss of contact between the endobags and the aorta (or between the two endobags), with consequent loss of seal and re-pressurization of the aneurysm. For these reasons, we also reported proximal displacement according to a less conservative (≥4 mm) definition that we have previously used for fenestrated EVAR and EVAS[11,21]. Interestingly, IFU 2016 compliant patients displayed approximately half the incidence of proximal displacement of the rest of the patients, regardless of definition (≥4 mm or >10 mm).

Whilst proximal stent displacement may be of particular relevance in short aortic necks, its potential clinical impact would also depend on the length of endobag/aorta apposition at the landing zones (the “seal”). In our experience, however, on CT scans, it is not always possible to measure length of seal, particularly in narrow necks, where the contour of endobags is difficult to define. We thus decided not to include this variable in the manuscript, as we were not confident on our ability to measure it reliably

The incidence of proximal displacement we demonstrated should be interpreted in context, by comparing it to that of post standard EVAR, when this is measured with similar criteria. A recent systematic review demonstrated an 8.6 % incidence of post-EVAR proximal displacement (≥5 mm) at 1-3 years; this was associated with poor anatomy and, unlike in our study, with type Ia endoleaks[22].

We also observed a significant incidence of aneurysm growth in our series, but only three late endoleaks. It is generally thought that aneurysm growth rarely occurs in absence of aneurysm perfusion and pressurisation. It is also accepted that aneurysm pressurisation post-EVAS can occur in absence of a visible endoleak[23]. Our findings thus suggest that even small degrees of proximal displacement may be clinically significant. It is possible that small movements may allow blood to seep between the endobags and the aorta, or between the two endobags, effectively creating a wedge-like communication between the proximal circulation and the aneurysm. Even after thrombosis of such communication, aneurysm growth may occur, as thrombus is capable of transmitting pressure[24]. EVAS may thus behave differently from EVAR during follow up. Our group recently highlighted the potential effect of certain forces (such as gravity and vibration) on

implanted Nellix prostheses[25]; these would not be expected to have the same effect post-EVAR, due to the difference in mass between traditional endografts and the Nellix prosthesis. Whilst it is still unclear whether such effects have significant clinical consequences, their observation underlines that post-treatment evolution of aneurysms treated by EVAS may be different from that of aneurysms treated by EVAR.

Whilst it is logical to assume that aneurysm growth follows proximal displacement /migration, it is also theoretically possible that proximal displacement could be secondary to aneurysm growth, as such growth would create additional space for the stent/endobag complex to move into. In support of this theory, we observed aneurysm growth before proximal displacement in three cases. Unfortunately, our study cannot establish whether aneurysm growth was a cause or a consequence of proximal displacement. Further research is necessary to clarify this relationship.

Our findings confirm that there is a reduction in proximal displacement incidence when complying to the recently refined IFU, which was introduced after a higher than expected incidence of migration was observed in American pre-marketing studies[26]. However, proximal displacement rate in this group was still found to be at 30% despite adherence to the new IFU. Our results should encourage clinicians to pursue close surveillance even in patients treated within IFU for early detection of proximal displacement and AAA growth.

This study has obvious limitations, as it was retrospective, limited to a single centre and to a relatively small population. Its strengths, however, include the prospective nature of clinical data collection, ensuring comprehensive capture of clinical adverse events, the low rate of loss to follow-up for a retrospective study and the previously validated CT measurement techniques. It should encourage further research on post-EVAS follow up in order to fully understand the mechanisms that lead to treatment failure.

Conclusion

Infrarenal EVAS is prone to proximal displacement, particularly when performed outside IFU. This proximal displacement may cause aneurysm growth in absence of endoleaks. The definition of migration used for EVAR may be inappropriate for EVAS; a new consensus on definition and measurement technique is necessary. Clinicians should continue close surveillance post EVAS, particularly in patients treated outside IFU.

Table 1. *Pre-operative aortic anatomy.*

Anatomical feature	All patients	Patients outside IFU
Aortic neck length (mm)	27 (6-65)	29(6-65)
Infra-renal neck angulation (degrees)	34 (0-78)	32 (0-77)
Maximum neck diameter (mm)	27 (5)	28(5)
Maximum aortic lumen diameter (mm)	44 (14)	41 (14)
Maximum aneurysm diameter (mm)	60 (54-93)	63(54-93)
Aortic bifurcation diameter (mm)	28 (14-54)	30(15-54)
Maximum right common iliac artery diameter (mm)	16 (4)	16(4)
Maximum left common iliac artery diameter (mm)	16 (4)	16(4)

Values are expressed as median (range) or mean (standard deviation).

Table 2. *30-day complications.*

Variable	n.(%)	Details	
Complications	19(25)	Device/Aneurysm related complications: 1 contrast nephropathy 5 Limb ischemia 1 Left internal iliac coverage 2 Access site haematoma 2 AAA rupture (asymptomatic) 1 intraoperative ruptured endobag 1 Intraoperative stent balloon rupture 1 intraoperative rupture of distal external iliac artery	Other complications: 2 Acute kidney Injury 1 Paraparesis, acute coronary syndrome and neck of femur fracture 2 Hospital acquired pneumonia
Re-intervention	7(9)	1 evacuation of haematoma 1 Insertion of spinal drain and hip hemiarthroplasty 2 thrombectomy	1 femorofemoral bypass + fasciotomies 1 Angioplasty + stenting 1 Embolectomy
Endoleak	1(1)	Type Ia, resolved within 48h	
Death	0	-	

Table 3*. Incidence and extent of migration at any time.*

	Total patient number	**Migration n(%)**		**Median migration (range)[a] (mm)**	
		≥4mm	**>10mm**	**≥4mm**	**>10mm**
Left stent	73	31(42)	10(14)	7.6(4-30)	16(11-30)
Right stent	74	34(46)	13(18)	7.3(4-29)	15(10.2-29)
Per patient	75	42(56)	16(21)	7.5(4-30)	15(10.2-30)

[a]among patients with migration

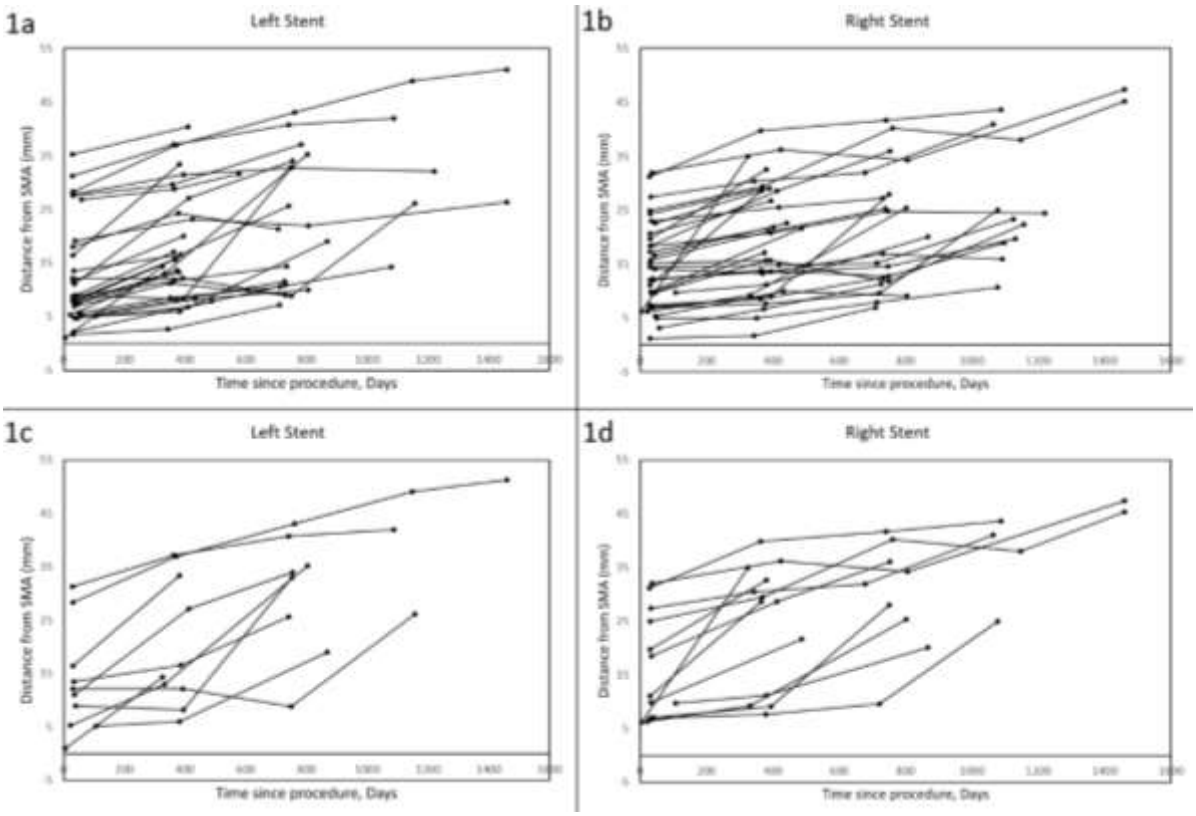


Figure 1. Distance between stent and superior mesenteric artery in patients with proximal displacement (1a and 1b) and migration (1c and 1d) over time.

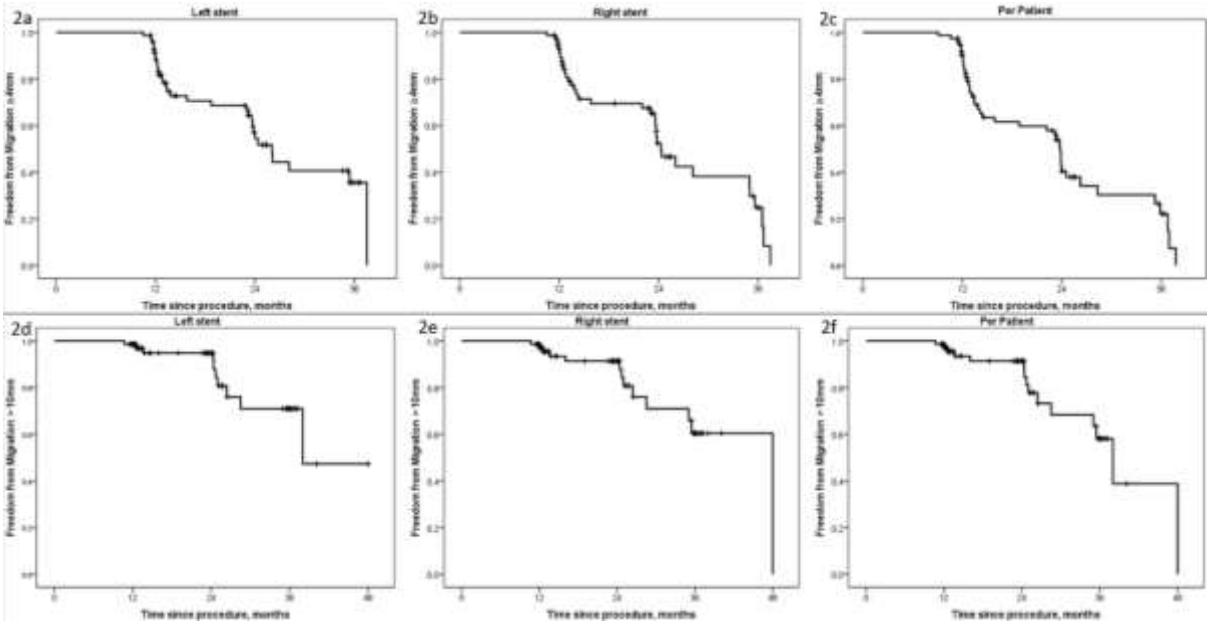
Table 4. *Migration at any time in different IFU groups.*

	Proximal displacement n./N (%)	Migration n./N (%)
IFU-2016 compliant	6/20 (30)	2/20 (10)
IFU-2016 non-compliant	36/55 (65)	14/55 (25)
IFU-2013 compliant (Non-compliant with IFU-2016)	22/35 (63)	9/35 (26)
Non-compliant with IFU-2013 and IFU-2016	14/20 (70)	5/20(25)

Table 5. *Late re-interventions.*
Follow-up range 12-48 months, median: 24 months

	Migrated cohort				Non-Migrated cohort	
	≥4mm (N=42)		>10mm (N=16)		(N=34)	
Variable	**n.**	**Details**	**n.**	**Details**	**n.**	**Details**
Late Re-intervention	6	1 Conversion to open repair 1 repeated EVAS, 1 superficial femoral artery angioplasty 1 Limb extension, 1 Nellix-in Nellix ChEVAS 1 Femoro-femoral bypass	5	1 repeated EVAS, 1 superficial femoral artery angioplasty 1 Limb extension, 1 NINA ChEVAS 1 Cross-over bypass surgery	4	1 femoral thrombectomy and embolectomy 1 thrombectomy and Tibial bypass 1 External Iliac artery stent 1 tibial bypass
Endoleak	3	Type 1a	2	Type 1a	0	-
Late Death	5	not aneurysm related	2	not aneurysm related	3	not aneurysm related

ChEVAS: Chimney Endovascular aneurysm sealing: EVAS extending into the supra-renal segment using chimneys



Figures 2. Freedom from proximal displacement (2a, 2b, 2c) and migration (2d, 2e, 2f)

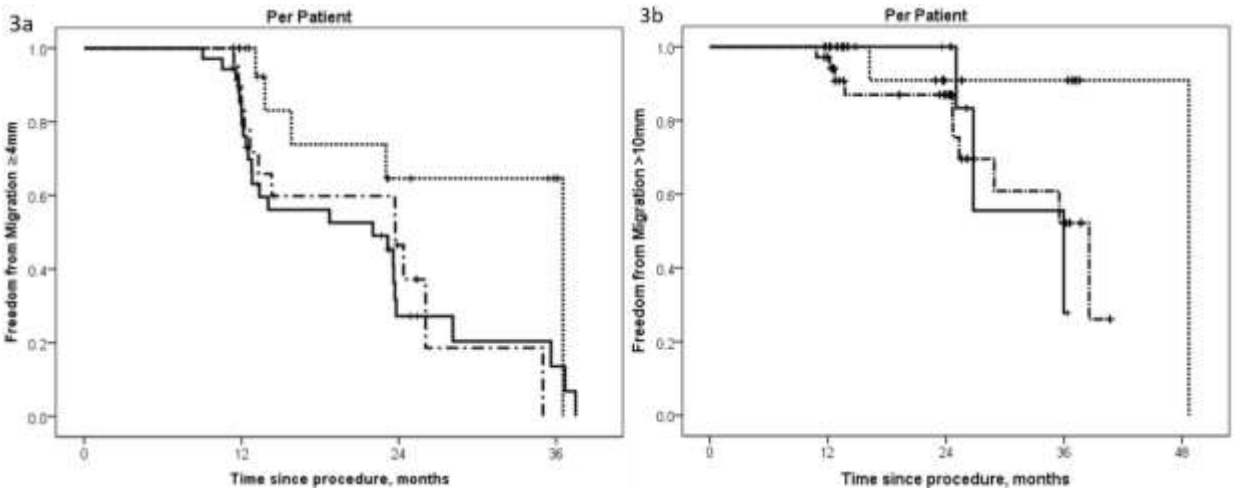


Figure 3. Freedom from proximal displacement (3a) and migration (3b) in different IFU groups. IFU-2016 compliant*: dotted line;* IFU-2013 compliant (Non-compliant with IFU-2016)*: line and dot line;* Non-compliant with IFU-2013 and IFU-2016*: continuous line.*

3a - Log rank (mantel cox) results: **IFU- 2016 compliant vs Non-compliant with IFU-2013 and IFU-2016: 0.037; IFU-2016 compliant vs IFU- 2013 compliant (Non-compliant with IFU-2016): 0.031; IFU-2016 compliant vs IFU-2016 noncompliant: 0.025;** IFU-2013 compliant (Non-compliant with IFU-2016) vs Non-compliant with IFU- 2013 and IFU-2016: 0.468.

3b - *Log rank (mantel cox) results:* IFU-2016 compliant vs Non-compliant with IFU-2013 and IFU-2016: 0.159; IFU-2016 compliant vs IFU-2013 compliant (Non-compliant with IFU-2016): 0.079; IFU-2016 compliant vs IFU-2016 non-compliant: 0.076; IFU-2013 compliant (Non-compliant with IFU-2016) vs Non-compliant with IFU-2013 and IFU-2016: 0.749.

Standard errors for each group at specified points can be found in appendix 1.

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